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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/674,277	02/13/2001	Dominique Therese Marie Frechon	P66034US0	5117

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EXAMINER

DUFFY, PATRICIA ANN

ART UNIT	PAPER NUMBER
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1645

DATE MAILED: 12/12/2003

13

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/674,277

Applicant(s)

FRECHON ET AL.

Examiner

Patricia A. Duffy

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-- Th MAILING DATE of this communication app ars on the cover sh et with th correspondence addr ss --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. ____.
 - ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
- a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 6.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). ____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

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DETAILED ACTION

The preliminary amendment filed October 30, 2000 has been entered into the record. Claims 2-19 have been canceled. Claim 1 is pending and under examination.

Priority

Receipt is acknowledged of papers submitted under 35 U.S.C. 119(a)-(d), which papers have been placed of record in the file.

Specification

The lengthy specification has not been checked to the extent necessary to determine the presence of all possible minor errors. Applicant's cooperation is requested in correcting any errors of which applicant may become aware in the specification.

The title of the invention is not descriptive. A new title is required that is clearly indicative of the invention to which the claims are directed.

Information Disclosure Statement

The information disclosure filed June 1, 2001 has been considered. A initialed copy is enclosed.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

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The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 1 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a written description rejection.

The specification discloses that the nucleic acid of SEQ ID NO:1 or 2 is a genomic DNA from *Escherichia coli* O157:H1 serotype situated on the enterohemolytic plasmid of 60 mD (page 5, first full paragraph). The claims are drawn to nucleic acids comprising SEQ ID NO:1, 2, their complements and the fragments and derived sequences thereof, differing by mutation, insertion, deletion and/or substitution of one or more bases and hybridizing under high stringency conditions with the sequences SEQ ID NO:1 and 2 respectively.

The Guidelines for the Examination of Patent Applications Under the 35 U.S.C. 112, ¶ 1 "Written Description" Requirement make clear that the written description requirement for a claimed genus may be satisfied through sufficient description of a representative number of species by actual reduction to practice, reduction to drawings, or by disclosure of relevant, identifying characteristics, i.e., structure or other physical and or chemical properties, by functional characteristics coupled with a known or disclosed correlation between function and structure, or by a combination of such identifying characteristics, sufficient to show the applicant was in possession of the genus (Federal Register, Vol. 66, No. 4, pages 1099-1111, Friday January 5, 2001, see especially page 1106 3rd column).

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It is noted that SEQ ID NO:1 and 2 are a DNA fragments from a plasmid. The specification, however, does not disclose the whole 60 mD plasmid or what genes SEQ ID NO:1 is from. Further, the specification does not disclose that SEQ ID NO:1 or 2 is drawn to a full length open reading frame. The claims reciting "comprising" read upon complete plasmid sequences having in common a nucleotide sequence of SEQ ID NO:1 or 2 or any hybridizing variant thereof from any source. With the exception of SEQ ID NO:1, 2 or specific fragments thereof, the skilled artisan cannot envision the detailed chemical structure of the encompassed polynucleotides, regardless of the simplicity of the method of isolation, absent further guidance. Since the claimed genus encompasses undisclosed genes, partial genomic sequences, and variants yet to discovered, the disclosed structural feature (i.e., the nucleic acid comprising SEQ ID NO:1, 2 and fragments thereof) does not constitute a substantial portion of the claimed genus. Absent a written description disclosing a representative number of nucleic acid sequences from this broad class of polynucleotides, the specification fails to show that applicant was "in possession of the claimed invention" at the time the application for patent was filed. In addition, claim 1 recites a nucleic acid comprising a nucleotide sequence comprising a sequence which hybridizes under high stringency conditions to a nucleic acid comprising a sequence as set forth in SEQ ID NO:1 or 2 as part of the invention. However, there does not appear to be an adequate written description in the specification as-filed of the essential structural feature of the instantly recited nucleic acids, nor a correlation between a particular structure and function. The genus of nucleic acid probes which would hybridize to a nucleic acid comprising SEQ ID NO:1 or 2 is very large, encompassing not only sequences with polymorphisms and mutations compared to SEQ ID NO:1 or 2, but also sequences having no shared sequence with SEQ ID NO:1 or 2 itself since the hybridization could occur within the non-SEQ ID NO:1 or 2 portion of the nucleic acid comprising SEQ ID NO:1 or 2. Further, no function is required of this hybridizing nucleic acid. Thus the genus of nucleic acids encompassed by this claim is extensive, and there does not appear

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to be any requirement that the nucleic acid probes share either a particular structure, a particular function, nor a correlation between some partial structure and a particular function. Consequently, SEQ ID NOs:1 or 2 again does not appear to constitute a substantial portion of the claimed genus. Since these various nucleic acids do not possess defined structures, fragments of these nucleic acids also lack adequate written description. The mere statement that a genus of nucleic acids is part of the invention and reference to a potential method for isolating some of these nucleic acids is not adequate written description of those nucleic acids. Vas-Cath Inc. v. Mahurkar, 19 USPQ2d 1111, makes clear that "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention. The invention is, for purposes of the written description inquiry, whatever is now claimed." (See page 1117.) The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed." (See Vas-Cath at page 1116.). Adequate written description requires more than a mere statement that it is part of the invention and reference to a potential method for isolating it. The nucleic acid itself is required. See Fiers v. Revel, 25 USPQ2d 1601, 1606 (CAFC 1993), and Amgen Inc. V. Chugai Pharmaceutical Co. Ltd., 18 USPQ2d 1016. Consequently, Applicant was not in possession of the instant claimed invention. Applicant is reminded that Vas-Cath makes clear that the written description provision of 35 U.S.C. 112 is severable from its enablement provision. (See page 1115.)

Claim 1 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The term "high" in claim 1 is a relative term which renders the claim indefinite. The term "high" is not defined by the claim, the specification does not provide a standard

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for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention.

Claim Rejections - 35 USC § 102 and 103

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claim 1 is rejected under 35 U.S.C. 102(b) as being clearly anticipated by Brunder et al (Microbiology, 146:3305-3315, 1996).

Brunder et al teach an isolated nucleic acid sequence that is 72.6 percent identical as compared with SEQ ID NO:1 (page 3308, figure 2 and alignment). As such, this reference anticipates "fragments" and hybridizing variants with respect to SEQ ID NO:1.

Claim 1 is rejected under 35 U.S.C. 102(b) as being clearly anticipated by Makino et al, (DNA Research, 5(1):1-9, Feb 28, 1998) in light of GenEMBL Accession Number AB011549.

Makino et al teach the isolation of and complete nucleotide sequences of 93 kb and 3.3 kb plasmids of an enterohemorrhagic *Escherichia coli* O157:H7 derived from Sakai outbreak. Makino et al teach extraction of DNA from the bacterium and isolation of the pO157 plasmid and subsequent sequencing of the plasmid, see page 2, Materials and Methods. Makino et al teach that pO157 is represented by EMBL Accession Number AB011549 (page 2, column 2, second full paragraph). The isolated plasmid inherently has a that is a fragment of hybridizes under stringent conditions because it comprises a

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sequence that is 98.7% identical as compared to SEQ ID NO:2 as evidenced by GenEMBL Accession Number AB011549 (see attached alignment).

Status of the Claims

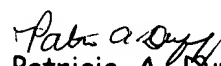
Claim 1 stands rejected.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Patricia A. Duffy whose telephone number is 703-305-7555. The examiner can normally be reached on M-F 9:30pm-6:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Smith Lynette can be reached on 703-308-3909. The fax phone numbers for the organization where this application or proceeding is assigned are 703-872-9306 for regular communications and 703-872-9307 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.


Patricia A. Duffy, Ph.D.

Primary Examiner

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